K093676

MAR 17 2010

# 510(K) Summary of Safety and Effectiveness
## TRIMED OMNITECH LARGE SYSTEM

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| **Submitted By:** | TriMed, Inc.<br>25864 Tournament Road, Ste. A<br>Valencia, CA 91355<br>(800)633-7221 |
| **Registration #:** | 2031009 |
| **Manufactured By:** | Biotech International<br>305, allée de Craponne<br>13300 Salon De Provence<br>France |
| **Registration#:** | 3005270144 |
| **Prepared By/Contact Person:** | Kelli Anderson<br>Phone: (661)312-7150<br>Fax: (661)254-8485 |
| **Proprietary Name:** | Omnitech Large or TriMed Compression Screw |
| **Classification:** | Class II: Bone, Fixation, Screws<br>HWC - Section 888.3040<br>Class II: Pin, Fixation, Smooth<br>HTY - Section 888.3040 |
| **Summary Preparation Date:** | March 10, 2010 |

### I. Indications for Use:

The TriMed Omnitech Large System is indicated for fracture fixation of large bone and large bone fragments, as well as fractures of the calcaneus, talus, and pelvis.

## II. Device Description:

The Omnitech Large screws are cannulated titanium compression screws available in diameters of 4.5 mm and 7.3 mm. The screws utilize two different thread pitches allowing the distal fragment to be drawn towards the proximal fragment with each turn of the screw. The conical shaped head increases the surface contact area with the cortical bone avoiding piercing of the cortical bone and the subsequent loss of compression. Currently the screws are made of TA6V ELI titanium alloy. Surgical grade stainless steel screws complying with ASTM F138 may be made available in the future.

## III. Substantial Equivalence:

K993106/K060736 - Smith & Nephew, Smith & Nephew Bone Plate System
K962011- Synthes (USA), Synthes 7.0/7.3 mm Cannulated Screws
K963172 - Synthes (USA), Synthes 4.5 mm Cannulated Screw

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TriMed, Inc.
% Ms. Kelli Anderson
Regulatory Affairs Consultant
25864 Tournament Road, Suite A
Valencia, California 91355

MAR 17 2010

Re: K093676
Trade/Device Name: TriMed Omnitech Large System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, HTY
Dated: February 17, 2010
Received: February 22, 2010

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K093676

Device Name: Omnitech Large

The TriMed Omnitech Large System is indicated for fracture fixation of large bone and large bone fragments, as well as fractures of the calcaneus, talus, and pelvis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093676